Attachment 1

REGION 9

QUALITY MANAGEMENT PLAN

U.S. Environmental Protection Agency
Region 9
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San Francisco, CA 94105

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INTRODUCTION

The Environmental Protection Agency is authorized to make decisions to protect the environment and public health. When decisions are based on scientific and other data, it is EPA policy to know the quality of these data. When EPA generates the data, it strives for data which meet project goals. With resource and time limitations, data should be collected only when necessary, and should meet the established objectives.

Agency QA Program. Concern over the reliability of data led to the development of an EPA Quality Assurance Program for environmental measurements performed by or for the Agency (EPA Order 5360.1, 1984). All EPA organizational units which perform or support environmental measurements must participate. Contracts and financial assistance agreements, including State programs, are required to address QA as well.

The Quality Assurance Management Staff (QAMS/ORD), under the Assistant Administrator for Research and Development, is the central management authority for the Agency QA Program. QAMS/ORD develops QA policies and procedures, and oversees the Agency-wide implementation of the QA Program in the program offices, Regions, and laboratories.

Regional QA Program Plan Update. Region 9's participation in the Agency QA Program included preparing a Regional QA Program Plan (QAPP), which was approved by QAMS/ORD in 1989. While the contents are still consistent with Regional goals, changes in some data collection activities and organization of Regional programs justified a formal review and revision. QA representatives designated by each of the Regional Divisions worked with Regional QA Manger to update the QAPP. Other subject matter specialists in the Region were interviewed to address Sections 3 through 6. This document results from that effort.

The QAPP has been revised to conform to QAMS/ORD's "Interim Draft EPA Requirements for Quality Management Plans," (EPA QA/R-2), to the extent possible. Where the Agency-wide QA Program previously addressed environmental measurements, the draft requirements span pollution control and remediation systems as well, and add quality elements associated with personnel, procurement and contracting, computer systems, and total quality management. The components are integrated into a "Quality System" which is documented in a "Quality Management Plan."

Region 9's QA Program, however, continues to center upon environmental measurements. Therefore this Quality Management Plan emphasizes those activities. Region 9 management has not been notified of the need to develop a QA program outside EPA Order 5360.1 and, therefore, any quality activities in those areas are occurring independently.

SECTION 1
QUALITY MANAGEMENT AND ORGANIZATION

1.1 REGIONAL QA GOALS AND POLICIES

Region 9's QA policies and activities regarding environmental data reflect the requirements of EPA Order 5360.1 and other Agency mandates. Basic goals and specific policies are summarized below.

BASIC GOALS

- Environmental data used in decision-making are of **known quality.**
- Only **necessary** data are collected.
- Data collected are of the type and quality needed and claimed, and **meet established objectives.**

POLICIES

Each program that generates environmental data will provide **sufficient resources** to support QA activities.

- A **QA plan** will be developed and approved for each environmental data collection activity prior to the initiation of data collection.
- The **intended use(s) and data quality objectives** (DQOs) of environmental data will be defined prior to collection of the data, and identified in the QA plan.
- **Cost will be balanced with technical quality** in integrating QA and QC procedures into environmental data collection activities.
- Projects and tasks involving environmental data collection will be accomplished in **conformance with approved QA plans.**
- **Oversight** of data collection activities will be performed and deficiencies or problems will be corrected expeditiously.

The Region believes that an appropriate level of QA should be applied to all environmental data collection activities (EDCAs). QA is performed in three stages during the EDCA:

I. Upfront QA planning occurs during the scoping and planning of the EDCA. Before any work is done, data needs, DQOs, and QA/QC procedures are established

and agreed upon. Upfront planning is critical in programs where standard procedures are not defined, or compounds of interest and action levels are not specified by regulations.

II. **QA/QC procedures are implemented** during the data collection process. Problems can be identified and corrected. The impact of field and laboratory techniques and sampling and analysis conditions on data quality are determined using field and laboratory QC samples and periodic audits. Oversight and corrective action can prevent improper procedures from becoming institutionalized.

III. **QA review** assesses the data quality and useability, based on the QA/QC information gathered during data collection. Through data validation the data quality is documented and communicated to the data user.

All three stages of QA are important in all EDCAs. The specific QA/QC activities for an EDCA or program, however, are a function of the DQOs. One stage of QA may be emphasized more than others on a given project, and the level of QA may vary from one EDCA to another. Therefore, the Region does not recommend a specific minimum level of QA support for all EDCAs; instead it requires that a level be defined and the decision documented, in a QA plan.

1.2 QUALITY ASSURANCE RESPONSIBILITIES AND ORGANIZATION

1.2.1 REGION 9 PROGRAM ORGANIZATION

The Region 9 program organization is shown in Appendix A. Regional management is tiered as follows, in descending order of authority:

Regional Administrator
Division/Office
Branch
Section
Team
Staff

The organization chart on page 1 of Appendix A shows the Division and Branches; the Sections are shown on the succeeding pages.

The Region 9 Laboratory, which recently moved to Richmond, California, is managed by the Laboratory Section of the Environmental Services Branch (LS/ESB) of the Office of Policy and Management (OPM). A separate QMP will be written to detail its activities; however, the Laboratory QA program is described generally in this document.

EDCAs are performed in every Division. Program elements as well as QA activities are implemented primarily at the section chief and staff levels, in conformance with general program guidelines set by the Branch Chiefs and Division Directors.

1.2.2 REGION 9 QA ORGANIZATION AND RESPONSIBILITIES

In any organization, management support is required for QA to survive. The responsibility for QA in Region 9 starts at the top, with the Regional Administrator (RA). The RA (and Deputy RA), by virtue of his/her position, is ultimately responsible for the administration of all Regional programs. The RA allocates the resources to support Regional functions, including QA.

The Regional Quality Assurance Manager (RQAM) provides a focal point for the implementation and monitoring of the Regional QA program, for technical training, and for auditing the Region's EDCA programs. The position of the RQAM is held by the Chief of the Environmental Services Branch under the Assistant Regional Administrator, Office of Policy and Management (Appendix A, page 5). The RQAM's responsibilities are identified in the following section.

The actual development and implementation of QA activities is shared by all Regional staff and management. The RQAM and QAMS/ESB interpret and disseminate the Agency and Regional QA management philosophy and policies and guide their application in the Region. The responsibility and authority for integrating QA into the program activities which involve environmental data collection belongs to the program managers (i.e., project officers, project managers, section chiefs, branch chiefs, and division directors.)

Among the QA responsibilities which the RQAM and QAMS/ESB promote, and the program managers perform, are the following:

- Develop **DQOs** for EDCAs.
- Develop, review, approve and implement **QA plans**.
- Ensure that proper **sampling and analytical procedures** are used and documented.
- Ensure that **data quality** is determined and known by decision-makers.
- Identify needs for, schedule, and participate in **audits** of data collection and QA procedures.
- Ensure that deficiencies or problems identified through audits are **corrected** expeditiously.
- Ensure that **QA training and technical support needs** are identified and prioritized so

that available training resources are used sufficiently.

The Region's quality assurance experts are located in QAMS/ESB. They advise the programs on QA matters, review QA documents, conduct QA audits of EDCAs and programs, and are responsible for the implementation of Agency QA policies and guidances in the Region. A second Section in ESB, the Laboratory Section (LS/ESB), contributes biological QA expertise. ESB's Field Serviced Team (FST/ESB) conducts the Drinking Water Laboratory Certification Program, DMRQA laboratory inspections, and field audits, and coordinates the Water Supply, Water Pollution, and DMRQA Performance Evaluation Studies. Most of the QA tasks for the Superfund program, including sample plan reviews, QA project plan reviews, and data validation, are performed by the Environmental Services Assistance Team (ESAT) contractor under QAMS/ESB direction. (QAMS/ESB staff are responsible for managing this contract, and for coordinating their work to meet Regional client's needs.) Several staff in the Air and Toxics Division have also been assigned QA review and oversight responsibilities.

Because the direct responsibility for assuring data quality rests with the program managers, the organization and lines on interaction for implementing program-specific QA/QC procedures is the same as for managing the programs within the Region. Effective communication between all levels of program staff, management, and the RQAM is therefore an essential element of QA.

1.2.3 RESPONSIBILITIES/AUTHORIZATION OF THE RQAM

The RQAM receives authority through a Position Description, which contains the duties and responsibilities of the position. These include the following:

- Serves as **manager** of the Regional QA Program and supervises a group of professional employees providing QA oversight and guidance for the Regional Office.

- Provides **training and guidance** on QA programs and policies that are consistent with Agency policies.

- Manages the development of the **Regional Quality Management Plan** (RQMP) and its implementation for all internal and external monitoring and measurement activities. Develops and submits the Regions's QA Annual Report to QAMS/ORD.

- Provides guidance in the development of **QA project plans** for Regional EDCAs as required by the Regional QMP. Reviews and approves (jointly with program managers or project officers), or designates Program staff and management to review and approve, all plans including those required in State grants, contracts and cooperative agreements funded by the Agency.

, Coordinates the review and approval of **alternate test methods** according to the requirements of the NPDES and Safe Drinking Water programs.

- Manages the Regional **performance evaluation sample program** used to audit the performance of laboratories in the Region which analyze samples for Agency programs. Interprets the results and oversees corrective action programs.

- Develops **laboratory and field audit strategies** to determine the quality of the work and adherence to established methods, protocols, and QA Plans. Follows up to ensure corrective action is taken.

- Directs the **evaluation of analytical data** generated by Regional laboratories, including contract laboratories, to determine validity, data quality and useability.

- Performs **system audits** of Regional and State environmental monitoring programs to ensure that proper QA procedures are used, and generated data is of the quality needed and claimed.

- Maintains **contact with State, Headquarters and Regional counterparts** to promote mutual understanding and coordination in developing and articulating QA requirements.

- **Represents** the Region or Agency on QA matters as required.

SECTION 2
QUALITY SYSTEM OVERVIEW

2.1 ENVIRONMENTAL DATA COLLECTION ACTIVITIES (EDCAs)

The major EDCAs in Region 9 are covered by the Regional QA program and are outlined in Tables 1A-6A (Appendix B) for a specific Branch or program.

2.2 QUALITY SYSTEM ELEMENTS

QA Project Plan (QAPjP). The planning of project-specific data collection activities is documented in QAPjPs. This allows appropriate technical and policy review prior to implementation, and consistency through the life of a project or within programs. When implemented as designed, the QAPjP is a detailed record of the scope and objectives of the data collection and the procedures and QA/QC used. QAPjPs are prepared using the guidance "EPA Requirements for Quality Assurance Project Plans for Environmental DataOperations, Interim Final", EPA QA/R-5, August 1994. In an EDCA which involves phases or episodes of data collection, e.g., a Superfund remedial investigation, sampling procedures are broadly addressed.

Field Sample Plan (FSP). It is necessary to identify sampling and analytical procedures specifically for a unique sampling event, and a FSP is employed for this purpose. FSPs contain event-specific information, as opposed to project-specific information contained in the QAPjP. FSPs may be required instead of or in addition to QAPjPs. FSPs are prepared using guidance "Preparation of a U.S. EPA Region 9 Field Sample Plan for EPA Lead Superfund Projects", 9QA-05-93, October 1994 and "Preparation of a U.S. EPA Region 9 Field Sample Plan for Private and State Lead Superfund Projects", 9QA-06-93, August 1993. The latter guidance is titled for "Superfund" projects, but is used for other programs as the information requested is applicable to all investigations (see Section 7.2 for further information).

The preparation of QAPjPs and FSPs is the responsibility of the Division or Branch program manager, grant recipient, or contractor. The responsibility for review and approval rests jointly with the Division program manager or site manager and the RQAM. Approval must occur prior to initiating data collection.

QA Program Plan (QAPP). Either a QAPP or QAPjP is required to meet the EPA QA requirements for contracts and grants. The QAPP outlines the structure of an organization's QA program and its underlying QA management policies. For most projects, the QAPjP guidance us used; however, a QAPP is preferable for some grants to State or local agencies. QAPPS are prepared using guidance "EPA Requirements for Quality Management Plans", EPA/R-2, August 1994.

Data Quality Objectives (DQOs). As defined by QAMS/ORD, DQOs are qualitative and quantitative statements of the quality of data needed to support specific decisions or regulatory actions. DQO development consists of determining what data are needed, why they are needed, how they will be used and who will use them; evaluating alternative measurement approaches based on cost and available resources; selecting the most cost-effective approach; and formulating data quality goals. DQOs are derived from a quantification of the desire to avoid decision errors.

For some routine monitoring programs, the National Program Offices have developed or will develop DQOs. Those DQOs are adopted by the Region and incorporated into QAPjPs and/or FSPs for these specific activities. For programs initiated in the Region, the program manager who is responsible for the EDCA is responsible for DQO development as part of the normal planning process. For programs with no defined DQOs, Region 9 has attempted to merge the DQO process with the development of the QAPjP.

DQOs are developed by the programs using "Guidance for the Data Quality Objectives Process for Superfund, Interim Final Guidance", EPA 540/G-93/071, September 1993 when developing QAPPs and QAPjPs for Superfund projects. The "Guidance for the Data Quality Objectives Process", EPA QA/G-4, September 1994 and Data Quality Objectives Decision Error Feasibility Trials Software (DQO/DEFT), User's Guide, Version 4, EPA QA/G-4D, September 1994 are used for non-Superfund projects. These documents and software guide one through the DQO process in preparation for developing the QAPPs, QAPjPs, and FSP. Site specific decision error limits can be determined for each site using the DQO process in these guidances. Outputs of the DQO process are documented in QAPjPs following the "EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations", EPA QA/R-5.

Standard Operating Procedures (SOPs). Data collection procedures can be standardized and published as written protocols for inclusion by reference in QAPjPs, contracts and similar documents, and for use as guidance and technical assistance documents. SOPs are prepared using "Guidance for the Preparation of Standard Operating Procedures (SOPs) for Quality Related Documents", EPA QA/G-6, November 1995. Program specific SOPs are prepared primarily by three groups: EPA Region 9 when performing the lead in an EDCA; States, Interagency agreements (IAGs) and grantees when performing the EDCA; and responsible parties of government entities (i.e., federal facilities) performing the EDCA while EPA retains oversight and decision making responsibilities. The responsibility for preparing, updating and approving SOPs rests with these parties. These groups are encouraged to develop program-specific SOPs for use. The Quality Assurance Office staff may assist in the preparation of site-specific and program-specific sampling and analytical SOPs. To avoid duplication of effort, an SOP prepared by one program may be utilized by another program, when appropriate. All SOPs related to EDCAs must be reviewed and approved by QAMS prior to their implementation.

Data Validation. Data validation is the assessment of the quality of data. It is performed by evaluating the field and analytical QC results and the completeness of the QC documentation, for the purpose of determining whether the data are acceptable for the intended uses. Data validation is scheduled by QAMS/ESB and performed by ESAT, either routinely or when requested by Regional program mangers.

Audits. The standard mechanism for assessing the effectiveness and adequacy of quality assurance measures is an audit. Several types of audits are scheduled and performed throughout the Region.

- The **management systems review (MSR)** evaluates the management of the QA program, i.e., management support, DQOs and planning documents, data quality assessment, audit procedures, and the effectiveness and consistency of corrective actions. MSRs are performed by QAMS/ESB. A goal of a minimum of one Regional program and one State agency program MSR per year is established. Additional MSRs are scheduled on an as-needed basis, or when problems are identified through other audit pathways.

- A **technical systems audit (TSA)** evaluates aspects of the actual performance of the EDCA, and includes field and laboratory audits. Field audits are scheduled and conducted by QAMS/ESB staff on an as-needed basis, such as when problems are identified through data validation. In addition, each Superfund contractor (ARCS, TAT, and TES) and several Potentially Responsible Party (PRP) contractors will be audited once per year. Laboratory audits are performed on the Superfund Contract Laboratory Program (CLP) laboratories at least once per year and on State drinking water laboratories every three years. In addition, QAMS/ESB audits laboratories working for PRPs, Federal facilities, RCRA owner/operators, NPDES dischargers and the UIC program.

- **Performance evaluation (PE)** verifies the ability of an analytical system to produce reliable data on a sample containing known concentrations of specific chemical constituents. The Region coordinates the regularly-schedules EPA-wide Water Supply, Water Pollution, and Discharge Monitoring Report QA (DMRQA) PE studies for laboratories which serve the Water programs. In addition, QAMS/ESB provides double-blind audit samples to check laboratory performance for various programs. While this is a very successful program, it is limited by the supply of PE materials.

2.3 QUALITY SYSTEMS FOR SPECIFIC REGIONAL EDCAS

In-House EDCAs. In-house EDCAs are data collection activities which are planned and performed by Regional 9 personnel. In-house activities support a variety of compliance, enforcement, audit and investigation activities, which are listed in Tables 1A-6A. (Activities involving EPA financial assistance or cooperative agreements, which are also listed in Tables 1A-6A, are considered extramural projects.)

An approved QAPjP and /or FSP is required for all Region 9 in-house activities. Since the documents are very similar, it is left to the judgment of the QAMS/ESB staff as to which documents are necessary. Examples are provided below.

- A **continuous data collection activity** is one whose procedures do not change significantly from year to year, such as routine compliance sampling, or monitoring efforts performed under one of the regulatory programs. For this type of data collection activity, one QAPjP which addresses the routine activities may be prepared. The QAPjP should be reviewed annually and revised when significant changes in procedures or organizational responsibilities occur.

- Sometimes QA issues are **site-specific**, such as for a Superfund remedial investigation. Such projects require a QAPjP for each project, which must be updated if the focus of the project changes significantly. FSPs may also be required, for a project which is completed in phases of sampling.

Extramural Projects. Extramural projects involve the expenditure of EPA funds in the form of grants, contracts, or formal cooperative agreements. Region 9's extramural projects that involve EDCAs are identified in Tables 1A-6A and 1B-6B.

The regulations for **financial assistance** (40 CFR, Parts 30 and 31) require applications for financial assistance involving EDCAs to include a QA document in the form of a QA narrative statement, a QAPP, or a QAPjP. The responsible project manager insures that a QA document is prepared and submitted to the Region as part of the financial assistance agreement. QAMS/ESB also reviews all grant project officer approval memos to determine if the QA requirements are being met. The project officer and the RQAM are responsible for review and approval of the QA documents.

The regulations for **contracts** (48 CFR, Part 1546) and the Contracts Management Manual (EPA Order 1900.2) require that all contract proposals in excess of $25,000 which include environmental measurements be reviewed by the RQAM for adequacy of QA/QC provisions prior to submission to the Contracting Officer. All QA documents incorporated into a contract proposal or required by the contract must be reviewed and approved by the project officer and the RQAM prior to the approval or initiation of the project. In addition, if no QA plan is required (i.e., no EDCAs) the project officer signs a form that is reviewed by the Contracting Officer.

Other extramural projects involving environmental data collection are periodically performed for the Region by other government agencies through formal cooperative agreements, and by parties in the private sector or the regulated community through administrative orders. EPA funds are not directly expended for the data collection activities. Substantial EPA involvement may occur during the performance of the project, however, and the data may be used by the Agency. The program manager is responsible for the quality of these data, by incorporating adequate QA/QC provisions into the formal agreement or document initiating the

project.

Requirements and Responsibilities for Quality System Elements. For each EDCA performed in Region 9, the associated QA/QC elements are identified in Tables 1B-6B (Appendix B).

SECTION 3
PERSONNEL QUALIFICATIONS AND TRAINING

The success of an environmental program depends on the capabilities of the individuals who carry it out. These include project and program managers, project officers, field and laboratory staff, and QA staff.

Management is responsible for ensuring that personnel involved in environmental programs and data collection have the needed academic background, training, and experience. The first step is the hiring process: supervisors define the duties, responsibilities and required performance levels, and human resources experts translate them into the appropriate position classifications and grade levels. The second step is on-going training, in the classroom and on the job. Staff members also have individual responsibility for maintaining and expanding their qualifications. The Human Resources Management Branch (HRMB) of the Office of Policy and Management conducts both the employment and training activities for the Region.

3.1 PERSONNEL QUALIFICATIONS AND CERTIFICATIONS

Technical staff are generally hired under scientific classifications: environmental scientist, life scientist, environmental engineer, chemist, etc. QA staff in QAMS/ESB consist of environmental scientists, chemists, and life scientists. The knowledge and qualifications necessary to receive these designations are dictated by Federal Office of Personnel Management classification standards.

The knowledges and certifications for technical personnel performing certain duties are further specified by Agency directives:

- Compliance inspectors/field investigators (personnel who conduct field activities that may lead to or support enforcement actions) (EPA Order 3500.1);
- Contract managers (EPA Contract Management Manual, Chapters 7 and 8);
- Health and safety (EPA Orders 1440.2 and 1440.3).

3.2 TRAINING

Technical training. Training requirements for technical staff generally are specified by Agency directives (cited in §3.1) as prerequisites for certification. Supervisors may also specify training for individuals on a case-by-case basis. Training courses developed to comply with Regional policies are generally non-technical, in areas such as TQI or cultural diversity.

Regional staff involved in environmental programs receive technical training by several routes. HRMB is the primary office which disseminates training requirements, arranges the delivery of training, and maintains personnel training records. With the exception of WMD, each program Division supports a training coordinator located in HRMB, who schedules program-specific trainings. Other technical training courses in the Region are scheduled by HRMB upon the recommendation of Regional program management and subject matter experts. Most are developed outside of the Region, e.g., OSWER training courses. Regionally-developed trainings are prepared and delivered by Regional program staff in their areas of expertise. Lastly, on-the-job training is an important component of each technical employee's work experience.

QA training. QAMS/ESB offers training to project officers, contractors, and States on specific QA-related topics (i.e., the preparation of QA project plans and sample plans, the use of validated data, technical information including sample collection, sample packaging and shipping, paperwork for sample collection, DQOs, and QA oversight activities). QA courses are also offered by QAMS/ORD (although rarely taken by Regional staff) on topics such as an orientation to QA management, DQOs, guidelines on the preparation and review of QAPPs, QAPjPs and SAPs, and the QA aspects of data collection and review.

The primary means for identifying needs for training provided by ESB are through the audit process and communications between ESB and the programs. Due to budget constraints, QA training is generally provided only in response to expressed needs. QA staff in QAMS/ESB, who conduct the majority of the QA review functions or oversees the ESAT contractor's performance of those activities, become qualified primarily through concurrent work assignments with experienced staff members and in-depth discussions and reviews by the RQAM.

Many of the Region's project managers and project officers lack the experience, training or time to personally carry out technical duties, or are reluctant to take ownership of QA functions. As a substitute, technical assistance from ESB is necessarily a strong and resource-consuming component of the Regional QA Program.

Professional development. To encourage professional development beyond initial qualifications, HRMB sponsors training to maintain or increase the work effectiveness of technical employees. The Regional Training Catalog identifies the following training categories:

- Communications
- Office of Civil Rights
- Management Development
- Financial & Contract Management
- Personal & Professional Development
- Legal & Regulatory
- Health & Safety
- Human Resources Development
- Science & Technology
- Information Systems Technology

Regional management supports the belief that regular training is needed to maintain and improve performance, by providing training information, and by paying costs of training taken in-house and also at external institutions. Rotational work assignments, such as the Intergovernmental Personnel Agreement Act (IPA) and career rotation programs, are also encouraged.

Documentation of training. Training completed is documented on EPA form SF-182, which is maintained in the personnel file. The effectiveness of the training is assessed by HRMB's review of the course evaluation portion of the SF-182 and by the supervisor's observation of work performance. Course evaluation forms are used to provide feedback to course instructors.

SECTION 4
PROCUREMENT OF ITEMS AND SERVICES

Procurement activities. The procurement activities in the Regional Office consist of small purchases (i.e., <$25,000). In addition, the Region 9 Contracting Officer (CO) administers six ARCS contracts and one ERCS contract issued by the Office of Acquisition Management (HQ). The statements of work for these contracts were developed by the Superfund Program at HQ.

Procurement process. Regional procurements take place in several phases. A user in a program Division first plans the procurement needs and develops the technical specifications, evaluation criteria, and any certifications needed. These are documented in a procurement request package (EPA Form 1900.8) which is reviewed and approved by the Branch Chief and Division Director and submitted to the CO for action. Changes to procurement documents undergo the same review and approval sequence.

Procurement of the requested items or services is undertaken by the CO, according to Federal and Agency regulations detailed in the Federal Acquisition Regulations (FAR), the EPA Acquisition Handbook and the EPA Contracts Management Manual. The procurement process is documented in the contracts file pertaining to the particular action.

Oversight of quality. The program user establishes the framework for monitoring the quality of items or services by incorporating inspection and acceptance criteria into the statement of work. When sub-contractors are used, the acquisition regulations require that responsibility be maintained by the prime contractors; therefore, there is no relationship between Regional staff and sub-contractors.

SECTION 5
QUALITY DOCUMENTATION AND RECORDS

5.1 RECORDS MANAGEMENT

5.1 REGIONAL RECORDS MANAGEMENT SYSTEM

A records management program is a framework to provide records storage and timely retrieval, secure storage and preservation of sensitive records, minimize potential loss or damage to records, and provide cost effective use of available storage space. All staff are responsible for insuring that Agency records are maintained in a proper manner.

Regional records management policies and guidance are contained in Regional Order 2160 (Records Management Policies and Procedures) (Appendix C) and in the Regional Records Management Manual. The Manual contains information on records management topics such as records and files management, transferring records to the Federal Records Center (FRC), requesting records from the FRC, and records retention and destruction. The disposition of records is governed by the General Records Retention Schedules and EPA Retention Schedules, which specify how long EPA records must be kept and when they can be destroyed.

Records management assistance and training are provided by the Regional Records Management Officer (RMO), who is located in the Information Resources Management Branch (IRM) of the Office of Policy and Management. The RMO also serves as the primary liaison with the local FRC, coordinates the transfer and retrieval of records, and assists offices in completing necessary forms and handling special situations.

5.1.2 QA DOCUMENTATION AND RECORDS

A computerized spreadsheet system for tracking the review status of QA documents (QAPPs, QAPjPs, FSPs, workplans, and other QA-related documents) is used by QAMS/ESB. Figure 1 is an example spreadsheet, showing the information recorded and tracked. The system also contains sorting and counting capabilities which enable workload and timeliness statistics to be calculated.

Approved QAPjPs and FSPs are maintained by the responsible officer or project manager, or by QAMS/ESB at the program client's request, and are subject to periodic review by the RQAM. Lists of QAPjPs approved for continuous EDCAs and of approved grant QA documents are maintained by QAMS/ESB to initiate periodic revisions of approved QAPjPs or to follow-through on commitments for new QAPjP submittals.

5.2 CONTROL OF QA GUIDANCE DOCUMENTS

QA guidance documents are developed for Regional use by QAMS/ESB in the absence of Agency-wide guidance, or when detailed Regional processes need to be documented. Examples include Regional guidances for preparing QAPjPs for Superfund remedial activities, FSPs for EPA-lead and private-party-lead sampling events, documentation requirements for preparing non-CLP laboratory data packages, and Region 9 data validation reports format.

Regional QA guidances are drafted by QAMS/ESB staff experienced in the subject area covered, and reviewed by the RQAM and other subject-area peers before approval by the RQAM for distribution. Document control format is used, and unique document control numbers are assigned to each document. Revisions are prepared and transmitted as needs are identified by QAMS/ESB staff.

SECTION 6
USE OF COMPUTER HARDWARE AND SOFTWARE

6.1 REGIONAL INFORMATION RESOURCES MANAGEMENT POLICIES

The Information Resources Management (IRM) Branch of the Office of Policy and Management (OPM) has the primary responsibility for setting policy and guidance for the management and development of computer-related program support. PC/LAN coordinators in each Division act as liaisons between IRM and their divisional co-workers. Database administrators for each program office coordinate activities relating to their associated databases. Since these are national databases, requirements are defined by the national program offices at HQ.

Regional data are collected, processed, and managed by the program offices. IRM manages the hardware, software and networking platforms. IRM also coordinates with the program offices on hardware and software issues, purchases and upgrades, and pilots programs.

IRM maintains the following Agency-wide guidances: "System Design and Development Guidance," "Supplemental Guidance to EPA's System Design and Development Guidance," "Operations and Maintenance Manual," and "IRM Policy Manual."

Use of computer hardware and software. The purchase of computer hardware and software by Region 9 and its contractors is governed by Regional Order R2100 (Information Resources Management Hardware Policy) and Regional Order R2100.1 (Information Resources Management Software Policy), which are provided in Appendix D. The Regional policies are designed to ensure that the computer hardware and software used meet program requirements, and are consistent with the Agency-wide standards they cite.

Assessment of impacts of hardware and software changes. Most requests for computer system development, maintenance, enhancements, etc. are initiated by clients in the program Divisions. IRM works closely with clients to determine their needs, options and implementation schedule.

Success or failure of system developments is measured by the level of client satisfaction. IRM has various mechanisms in place to monitor customer satisfaction, including surveys, outreach meetings to discuss IRM-related issues, solicit client feedback and resolve differences, and an open-door policy.

The assessment of the potential impacts of IRM changes is emphasized before implementation. Two regional senior level steering committees are in place that determine GIS and IRM policy and direction. Broad-based projects impacting the entire Region generally require support by senior level IRM steering committee members. In addition, prior

to changing a computer environment, the cost of the tool and training for the developers is measured against the amount of utility derived from the tool.

Region 9 utilizes two 5-year mission-based plans for IRM activities: 1) a 5-year plan developed and updated by OARM which is used as directional guidance, and 2) a Regional strategic plan which incorporates information resources initiatives.

Development of software. The software applications which are developed in Region 9 are small in scope. They are primarily user-oriented, and not utilized outside the Region. Database applications are developed using existing software only. A typical example is the Clipper-based QA document tracking system developed by IRM for the RQAM. Regional personnel are discouraged from developing their own software.

The development process includes the following steps:

- meetings with the user to determine user needs;
- development, validation, and verification of the application;
- preparation and delivery of user documentation;
- preparation by the developer of a manual on the development process.

IRM programming staff follow "Programming Guidelines" (1991). This Regional document parallels and simplifies EPA and Federal policies and procedures.

Standards for computer-generated data. The Regional IRM data standards are consistent with the Agency-wide standards: Wordperfect (word-processing), Dbase (database management), Lotus (spreadsheet), Crosstalk (communications), and ARCInfo (GIS). Regional contracts require conformance with the Regional and Agency standards for hardware, software, and data delivery format. Seven-point justifications for computer related purchases require IRM concurrence. The monitoring of compliance is the responsibility of the project officers.

6.2 ENVIRONMENTAL DATA STORAGE AND RETRIEVAL

Monitoring data are in some instances stored on computer databases. Some are databases developed by HQ program offices (e.g., STORET) while others are developed for specific users (e.g., Superfund contractors for data from remedial investigations). The database software includes QA routines. These routines are assumed by the user to be adequate for the intended use of the database. The responsibility for quality control of data entry and corrections belongs to the program Divisions which maintain the databases.

SECTION 7
QUALITY PLANNING

7.1 REGIONAL PLANNING PROCESS

Annual program planning. Most Regional work activities are mandated by policy guidance, tracked commitments to HQ, and Branch Operating Plans (BOPS). A BOP is prepared by each Branch prior to the start of a fiscal year. It contains estimates of the work activities for that year. Ideally, the BOP is developed in consultation with the Branch's customers and suppliers. The ESB FY 94 Workplan (Appendix E), which ESB provides to its program customers for comment during preparation, is an example of a BOP. In §III of the Workplan, the units of measure depend on the item, e.g., Item 1a refers to one meeting, while Item 3e refers to 15 grant applications in the first quarter.

The primary vehicles for annual planning in the Region are the budget process, the Strategic Targeted Activities for Results System (STARS), and the State/EPA Agreement process. The Deputy Regional Administrator allocates resources to each Division for the management and operation of specific programs, based on the Region's anticipated budget. Program managers must then balance their available resources with their need for support, e.g., QA support from QAMS/ESB, to meet program goals and STARS commitments. Negotiations between customers and suppliers within the Regional Office result finally in work commitments.

QA annual planning. Annual planning for QA is important to ensure that available resources are used to accomplish the most critical QA activities, and that major deadlines are identified. The Region's QA Annual Report and Workplan (QAARW) is prepared in conjunction with QA annual planning in the Region. It is written by QAMS/ESB with Regional and State input, and is due to QAMS/ORD on November 1st of each year. The QAARW chronicles the QA activities completed, significant highlights and problems, updates to the Regional QMP, and projected activities for the following year.

7.2 PLANNING PROCESS FOR TECHNICAL ACTIVITIES

Data Quality Objectives. Region 9 has integrated the development of DQOs for projects involving EDCAs into the normal process of project planning and design. EDCAs generally begin with project scoping, where project specific DQOs are determined in accordance with EPA QA/G-4, "Data Quality Objectives Process", September 1994 or "Data Quality Objectives Process for Superfund, Interim Final Guidance", September 1993,

EPA 540/G93/071 depending on the program involved. The sampling objectives, design strategy for optimizing the information obtained, and the acceptable levels of error (i.e., determining the number of samples to be collected to meet field and lab stated QA/QC criteria with available resources) are determined by the stakeholders, project managers, regional QA staff, risk assessors and other data users, in the project during this process. Outputs of the DQO process are documented in QAPjPs following the "EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations", EPA QA/R-5.

DQO's are qualitative and quantitative statements which specify the acceptable error rates associated with environmental measurements for decision making purposes. Sampling designs and quality control criteria for field and laboratory methods and procedures, derived from site-specific DQOs, should be included in planning documents such as QAPPs, QAPjPs or FSPs. Continued communication among project managers, sampling, analytical, and QA staff is necessary to ensure common expectations and understanding of logistics and schedules.

QAPjPs and FSPs. An approved QAPjP and/or FSP is required before implementation of an EDCA. These documents are prepared by technical staff responsible for performing the EDCA, and submitted to the RQAM for review through the project manager or officer. QAPjPs and FSPs are prepared using the EPA QA/G-4 guidance which take the EDCA planner through the DQO process for determining project objectives and acceptable levels of confidence for the data to be collected.

QAPjPs are formatted and prepared following "EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations", EPA QA/R-5, August 1994.

FSPs for Superfund projects are formatted and prepared using "Preparation of a U.S. EPA Region 9 Field Sample Plan for EPA-Lead Superfund Projects", 9QA-05-93 (Appendix F), while other programs use "Preparation of a U.S.EPA Region 9 Field Sample Plan for Private and State Lead Superfund Projects", 9QA-06-93 (Appendix F). The latter guidance is titled for "Superfund" projects, however, it may be used for other programs as the information requested is applicable to all investigations. The graded approach is used for non-superfund investigations. "Graded" means the stringency or rigorousness of the QA/QC measures applied during the investigation are based upon the data quality objectives. For example, the QA/QC performed during decontamination and sample handling would be more stringent for a drinking water enforcement investigation than a routine waste water quality monitoring event due to the nature of the investigation and the lower level of contaminants being tested.

Planning documents submitted by the programs such as the QAPjPs or FSPs containing QA/QC requirements and procedures are largely reviewed and approved by QAMS prior to collection of environmental measurements. Personnel in media divisions authorized by QAMS may also perform reviews. This review and approval process applies to EPA funded projects, including grants, IAGs, and other EDCAs in which EPA plays an

oversight/decision maker role. A multi-disciplinary approach is used by QAMS to perform the reviews. Internal peer reviews are performed by QAMS staff to ensure QA recommendations on various fields (statistics, marine biology, engineering design/construction, field and lab methodologies, etc.) are sound and add value to the project.

Contractor conversion positions granted in 1994 have increased the number of documents reviewed by QAMS. QAMS' outreach efforts have increased the Region's awareness to address QA in environmental data collection activities and have resulted in an increase in document review workload. A percentage of QA planning documents are reviewed by the ESAT contractors to supplement QAMS' effort. The Region exercises appropriate contract management controls which are approved by the contracting officer. All comments generated by contractor personnel are reviewed by QAMS personnel to ensure that no inherently governmental decisions are made by ESAT. These comments are edited and modified by EPA reviewers as necessary prior to being released to our clients. ESAT does not make any decisions on approval of QAPPs, QAPjPs, FSPs, and Workplans.

After approval by QAMS/ESB staff or other EPA authorized personnel, the final documents are archived by the project manager.

Health and Safety Plans. Regional FSP guidance requires the preparation and submission of a site health and safety (H&S) plan whenever the protection level is above "D" (i.e., A, B, C). Information on H&S plan preparation can be obtained through the Regional Health and Safety Officer, currently Richard Taft (415) 744-1491. The plan is reviewed and approved by the Regional Health and Safety Officer for EDCAs performed by Regional staff. Review and approval of health and safety plans prepared for EDCAs performed by contractors or other non-EPA units are the parent organizations' responsibility.

SECTION 8
QUALITY IMPLEMENTATION, ASSESSMENT AND RESPONSE

8.1 IMPLEMENTATION
8.1.1 PROJECT MANAGEMENT

It is important that an EDCA be implemented in accordance with an approved QAPP, QAPjP or FSP. The project manager pursues conformance by assigning leadership roles and responsibilities for field laboratory and QA activities in the QAPP or QAPjP, and by performing oversight during performance of the EDCA through field and laboratory audits, the use of QC samples, and data quality audits. Independent performance monitoring of selected projects by QAMS/ESB also encourages conformance.

8.1.2 STANDARD OPERATING PROCEDURES

Specific field and laboratory data collection procedures and technical operations such as data validation can be documented as standard operating procedures (SOPs) for inclusion by reference in QAPPs, contracts and similar documents. SOPs are a means of establishing uniformity throughout an EDCA and of integrating quality control provisions into routine operations.

The party that implements the procedure or that generates the QAPP or QAPjP is responsible for the preparation of SOPs. Use of existing SOPs is also encouraged. SOPs provide specific step-by-step procedures for carrying out generic methods for sample collection, field or laboratory analysis, data review, data assessment, etc. SOPs for the environmental data collection activities are referenced in site-specific QAPPs or QAPjPs. When the scope of work changes which require the use of different or additional lab and field methods or if new regulations necessitate the use of new methodologies, existing SOPs should be reviewed and modified accordingly. Effective and reliable SOPs help eliminate uncertainties by minimizing inconsistencies in performance or misapplication of laboratory and field methods. SOPs help to ensure that data of known and adequate quality will be generated by defining the sequence of procedures for field and laboratory personnel to follow.

SOPs can be written simply so that a potential user with basic experience and training can readily understand and apply the procedures to meet its full intent. Also, SOPs should be consistent with sound scientific and engineering principles and with current EPA guidelines and regulations. Procedures developed as SOPs, are reviewed and approved by the RQAM through the approval process. In routine monitoring programs such as those under state and IAGs, SOPs are reviewed concurrently with the review and update of the parent QAPP or QAPjP.

SOPs developed for EDCAs at Region 9 should be consistent with the "Guidance for the Preparation of Standard Operating Procedures (SOPs) for Quality-Related Documents", EPA QA/G-6, November 1995. The SOPs, should at a minimum, include the following:

1. Title Page;
2. Control Documentation;
3. Table of Contents.

The contents should include:

a) Purpose of Standard Operating Procedures;
b) Applicability;
c) Procedural information;
d) QA/QC practices to be applied;
e) Checklists used (if applicable);
f) References used.

The following EDCA related SOPs have been developed by Region 9 ESB prior to the distribution of the EPA QA/G-6 guidance:

Field Related SOPs

1. Field instrument calibration (pH, conductivity, temperature, turbidity, and HNU);
2. Performing RCRA Inspections (November 1995, Revision 1);
3. Field Analytical Support Project (FASP) SOP for determining semivolatiles in soil, F93027/F93032;
4. FASP SOP for determining PCP in soil, F93026;
5. FASP SOP for determining PCB in soil, F93031;
6. FASP SOP for determining VOC in soil, F93013;
7. FASP SOP for determining VOC in water, F93001;
8. FASP SOP for determining Pest/PCB, F93006;
9. FASP SOP for preparing samples for Pest/PCB analyses, F93005.

Laboratory Related SOPs

1. Document Control;
2. Maintenance of Laboratory Records and Logs;
3. Sample Receipt and Tracking;
4. Laboratory Analysis for Organics and Inorganics;
5. Technical and Managerial Review of Data;
6. Statistical Review of Quality Assurance Data;
7. Internal System Evaluation;
8. Prevention of Sample Contamination;
9. Routine Maintenance of Laboratory Support Equipment;
10. Labware Cleaning protocols;
11. Disposal of Samples and Hazardous Waste in the Laboratory;
12. Data Validation.

QAMS anticipates that the following SOPs will be drafted as time permits and in accordance with EPA QA/G-6:

1. Performing document reviews;
2. Optimizing performance evaluation samples and how to procure them;
3. Performing QA split sampling;
4. Performing sample collection.

Review and Approval of EDCA Related SOPs. The review and approval policies for SOPs developed by the parties referenced in Section 2.2, SOP follow:

When EPA is the lead agency for the EDCA, field SOPs are usually prepared by EPA contractors or EPA personnel. If EPA contracts with non-CLP laboratories or when data review or validation is conducted by an EPA contractor, then laboratory SOPs or QA manuals and validation SOPs, respectively, are requested by the project manager and submitted for review by QAMS. SOPs should be submitted to QAMS as part of or as an addendum to the QAPP or QAPjP for review.

Where the states and other grantees perform EDCAs or IAGs, field SOPs are usually prepared by states and grantees or their contractors responsible for the EDCA. Lab SOPs should be prepared by personnel who operate the lab. If the states or grantees use contract laboratories, then laboratory SOPs and QA manuals should be requested of them. States or grantees can independently approve the use of their contractors SOPs under EPA grants only when this function is stated in the approved quality management plan; otherwise SOPs should be submitted to QAMS as part of or as an addendum to the QAPP or QAPjP.

Where EPA has oversight responsibilities and is the final decision maker for EDCAs performed by governmental or responsible parties, the SOPs are prepared by the government agency, responsible party or their contractors performing the EDCA. Field and laboratory SOPs and QA manuals should be requested by EPA project managers and submitted as part of or as an addendum to the QAPP or QAPjP to QAMS for review. These SOPs and manuals should also be reviewed by the project managers within the individual agency or organization conducting the EDCA to involve them and make them aware of their role in the QA oversight process.

All review comments should be satisfactorily addressed by the authors of the SOPs. Final approval should be given by QAMS or authorized program before any SOP is put into actual use.

Frequency of SOP Review and Update. EDCA related SOPs are reviewed every year by the party responsible for performing the EDCA to ensure that the SOPs are still adequate and meet current standards. SOP revisions are prompted when the following occur and should be reviewed yearly:

a) significant update/revision of procedures to improve method efficiency or due to instrument up-grade or new technologies.

b) modification of methods or previously approved SOPs to address project or site-specific needs (e.g., need a lower detection limit for an analytical method).

c) promulgation of new regulations or their revisions requiring the addition of new or revisions of existing SOPs due to more stringent and higher environmental standards.

SOPs affected by these criteria will need to be updated during the year of the change. The one year rule for revision and update may be waived on a case-by-case basis due to resources constraints involved or where the change is so minor that the quality of the data generated is unaffected. In these cases the minimum frequency for update will be every three years. When changes occur, EDCA related SOPs are revised and submitted to QAMS for review and approval as addendums to the QAPP or QAPjP.

8.2 QUALITY ASSESSMENT AND RESPONSE

All EDCAS require a mechanism for monitoring the effectiveness and adequacy of the QA measures integrated into the program. The standard oversight mechanism is the audit. An audit compares the data quality needs of the program and the procedures for obtaining the data with the actual procedures and the data quality obtained. An audit can pinpoint the weak link in the data collection activity, whether it be at the managerial, sample plan preparation, sample collection, analytical, data review, or data usage stages.

Overall, the audit is expected to: identify strengths and weaknesses; cause corrective actions to be taken to alleviate problems, facilitate the initiation of changes to enhance the QA program; serve as a vehicle for providing technical assistance; enhance awareness and understanding of QA/QC policies and procedures; and provide a measurement of the effectiveness of QC in assuring the quality of data.

Audits or reviews are scheduled and performed on Regional programs as needed and as resources allow to provide an overview of the effectiveness of the QA measures adopted by each program. Four types of audits or reviews are conducted, as explained below.

8.2.1 MANAGEMENT SYSTEMS REVIEW (MSR)

In order to assess whether the goals of the Agency's mandated QA programs have been met, the Region conducts periodic MSRs to evaluate management aspects of its QA program. More specifically, the MSRs assess the effectiveness of the procedures used in quality planning for

collection of environmental measurements (DQO process). The MSRs also evaluate the degree of senior management support for the implementation of the Region's quality system. The MSRs obtain an accurate description of staff's understanding of QA roles and responsibilities and the staff's skills and knowledge of QA practices and principles required for effective execution of QA activities. The MSRs also evaluate adherence to the Region's QA documentation requirements. The MSRs further reveal the proficiency of the Region's QA system in auditing, identifying errors and rectifying QA/QC deficiencies.

MSRs will be conducted for both EPA and non-EPA funded EDCAs in which EPA has an oversight responsibility or use the environmental data for decision making purposes. EPA funded EDCAs include work done under cooperative agreements such as grants and IAGs. For non-EPA funded activities conducted by federal facilities, the Region's QAMSRs assess EPA's QA oversight responsibilities while the federal facilities have the responsibility to assess their own QA system. It is required that the federal facility Quality Assurance Management Systems Review report be submitted to EPA for review and comment.

The Regional MSRs will be conducted in accordance with the "Guidance for Preparing, Conducting, and Reporting the Results of Management System Reviews", EPA QA/G-3, January 1994. At a minimum, one MSR will be performed on a Regional program and on an EPA funded state program each year. However, an MSR will be triggered by severe and persistent QC failures or non-compliance identified through routine and standard field/lab audits and other quality checks.

MSRs, in most cases, will be conducted by Regional QA personnel. The audit process begins with the RQAM contacting the management of the office and/or state to be audited. The RQAM then informs them of the audit to be performed and the purpose of the MSR. Participation by non-QA regional staff members will be encouraged and agreed upon by QAMS and the office on which the MSR will be conducted. When performing an MSR on programs in the Region, non-QA staff will be selected from programs other than that which is being audited. When the states are audited, Non-QA staff members directly related to the state program being evaluated will be allowed to participate in the MSRs.

Following the agreement between QAMS and the office to be reviewed, the audit is scheduled and performed by QAMS. The MSR team, comprised of QA and, in some cases, non-QA staff, will prepare a draft QAMSR report to be submitted to the director of the division in which the audited program is located, and to the Assistant Regional Administrator. The report resulting from an MSR will describe when, how, and by whom the audit was conducted, what specific items were reviewed, a summary of the audit (overall program assessment and significant findings), and recommendations for corrective actions as necessary. The program managers and/or state agency should prepare a response to the recommendations contained in the MSR report within the time frame agreed upon between the RQAM and the program or state. The QAMSR team will address the response and finalize the report.

8.2.2 TECHNICAL SYSTEMS AUDIT (TSA)

The technical systems audit (TSA) evaluates the actual data collection aspects of the EDCA. This includes field and analytical procedures, planning documents (QAPPs, QAPjPs, FSP, etc.), calibration records, sampling and measurement procedures general laboratory cleanliness, equipment and facilities, maintenance and repair records, and control charts.

Field audits are conducted to verify that sample collection, shipping, and associated procedures are consistent with those specified in the QAPP, QAPjP or FSP. The EDCAs for which field audits are regularly performed are identified in Tables 1-6. Appendix G contains the QAMS field audit strategy and checklists used. The actual frequency of audits scheduled depends on the resources available for the FST/ESB and QAMS/ESB field audit staff.

On-site audits of Contract Laboratory Program (CLP) laboratories are performed by the Regional CLP Technical Project Officer (CLP-TPO) who is located in QAMS/ESB, at least once a year. Standard CLP audit checklists are used, in conjunction with on-going reviews of data validation reports and other contract compliance information. The evaluation reports from these audits are used to identify and remedy laboratory performance problems. Repeat audits are made on an as-needed basis to resolve laboratory problems. When problems are identified, the CLP-TPO oversees the implementation of laboratory corrective action, or contract action if necessary.

Audits are conducted of non-CLP laboratories including those used by Superfund PRPs and Federal Facilities, RCRA owner-operated laboratories, and others, according to an audit strategy (described Appendix H), or as requested. The CLP audit checklists are used as the basis for performing the audits.

Laboratory certification audits of State drinking water laboratories are conducted by laboratory certification officers in FST/ESB and LS/ESB, once every three years. In addition, annual overviews of certification audits of private laboratories by State certification staff are conducted. Procedures and checklists for these audits are defined in the laboratory certification manuals published by NERL-Cincinnati.

For both field and laboratory audits, prepared reports describe when, how and by whom the audit was conducted, what specific procedures were reviewed, a summary of the findings, and recommendations for corrective action. The audit report is transmitted to the audited office, the program manager, and the project officer, as appropriate. Follow-up activities vary with the project.

8.2.3 DATA VALIDATION

Data validation is a process of reviewing the raw data and QC documentation, and assessing the quality of data generated. It is scheduled by QAMS/ESB and performed by ESAT. Data validation is performed automatically on intramural Superfund and RCRA data,

and as requested by other Regional program managers. The primary purpose of this type of audit is to determine if the data collected is acceptable for its intended use.

Data validation consists of an evaluation of the completeness of the documentation of field and analytical procedures and quality control results, and a comparison of the data quality of the collected data with the project DQOs to determine if the DQOs are met. This evaluation and comparison results in the determination that the data met the DQOs, the data use is limited, or the data should be rejected.

The Superfund "Functional Guidelines for Evaluating Laboratory Data" for CLP organic and inorganic analyses are used to validate Superfund data, and are the basis for the validation procedures for other types of data. Appendix I contains the required composition for data packages prepared by non-CLP laboratories for data validation by the Region.

Data validation results may be used to determine the need for changes in the design and performance of data collection efforts or in the use and documentation of QC procedures. Problems identified through data validation may also trigger follow-up to address sample collection or laboratory problems, and contractor performance.

8.2.4 PERFORMANCE EVALUATION

The performance evaluation assesses the ability of an analytical system to obtain reliable data. It consists of providing a reference or performance evaluation (PE) sample(s) to the laboratory for analysis. The PE sample contains known concentrations of chemical constituents or pollutants of concern and will normally be in the appropriate media (e.g., soil, water). The analytical results obtained by the laboratory audited are compared to the known concentrations of the specific parameters contained in the PE sample(s) to determine if the laboratory properly identified and quantified the constituents within established or calculated control limits.

Performance evaluations are conducted on a regular basis or on an as-needed basis depending on the laboratory and the program involved. The Region coordinates the regularly-scheduled Water Supply and Water Pollution PE Studies, in which participation is mandatory for designated laboratories, for the Agency-wide Public Water Supply and NPDES programs. Procedures for these evaluations are dictated by NERL-Cincinnati. Laboratories which exceed the statistical acceptance limits are requested to evaluate the source of differences and report their corrective actions to the Region.

Audit samples of specific parameters are obtained from appropriate EPA ORD laboratories by QAMS/ESB when needed by the program managers to support data validation. In special situations QAMS/ESB prepares PE samples from neat materials supplied via the Superfund QATS Laboratory in Las Vegas. These samples are taken to the field and submitted blind or double-blind with field samples, to the laboratory. Their use is limited by

the availability of the reference materials. Results and/or data packages submitted to QAMS/ESB by the subject laboratory are evaluated for consistency with pre-established acceptance windows. A written report describing the assessment and implications is submitted to the client.

SECTION 9
QUALITY IMPROVEMENT

Regional management has adopted Total Quality Management (TQM) as a primary method to build and improve its infrastructure, while incorporating a broader level of involvement in its efforts to address environmental problems. A Regional Quality Coordinator is designated in HRMB, who serves as an advocate and advisor for TQM implementation in the Region, and bridges the activities occurring in the rest of the Agency.

The Region envisions fully integrating the concepts and tools of TQM, in common-sense, practical day-to-day applications. This means a working environment where:

- Employees are fully trained in and employ TQM principles as part of the basic organizational culture.

- Quality action teams (QATs) are formed, used, and then dissolved in a fluid manner.

- Employee performance standards and recognition systems are aligned with TQM.

- Senior managers actively provide support and leadership through the empowerment of staff, encouraging-rewarding planned risk taking and innovation, and fostering open lines of communication.

In order to achieve the vision, the following activities are performed:

- **Training.** Basic training (the "Basic Quality Course" [ODI]) is offered to interested Regional staff, States, and Tribal Nations. An "Executive Course on Quality" is offered for Senior Managers. Formal training is also provided for TQI facilitators in the techniques of conducting the basic training and in facilitating QATs. A TQI Resource Section is planned for the Regional Library.

- **Applications and Support**. QATs, both formal and ad hoc, are in continual formation and closure to pursue solutions to problems identified in any area. Success stories and lessons from these experiences are gathered by the Regional Quality Coordinator for dissemination. Outreach sessions are conducted by the Coordinator, to discuss and encourage common-sense, practical approaches to applying TQI in day-to-day activities. Outreach and partnership efforts are established with state agencies and tribal nations to cooperate on joint TQM projects and QATS.

- **Assessment**. Regional self-assessment surveys are conducted or in development, to provide feedback on the implementation and effectiveness of TQM in the Region.

- **Information Exchange**. A Quality Coordinator's Network among Regions promotes the sharing of ideas. The Region also takes a leadership role in Agency-wide TQM implementation activities.

SECTION 10
REGIONAL LABORATORY

10.1 MISSION AND OPERATIONS

Mission. The mission of the Regional Laboratory is to perform sample analyses in support of Regional environmental monitoring and enforcement efforts. The Laboratory provides analyses for Regional programs under any of the following environmental regulations.

- Clean Water Act (NPDES, Water Quality Monitoring Program)
- Safe Drinking Water Act (Drinking Water, Underground Injection Control)
- Resource Conservation and Recovery Act (RCRA Program)
- Superfund Amendments and Reauthorization Act (Superfund Program)
- Toxic Substances Control Act
- Clean Air Act

The Laboratory strives to support the Region's non-routine analytical needs, such as quick analytical turnaround or analysis of unusual matrices. The types of samples received by the Laboratory are highly variable, but may be generally categorized as environmental samples, waste samples, and samples of pure product or material. Specific sample types include water, animal and plan tissue, soil and sediment, dust, oil, solid and liquid wastes, and products in all physical states.

Facilities. The Region 9 Laboratory is located in Richmond, California, across the San Francisco Bay from the Regional Office. Twelve ESB staff and 30 ESAT staff are assigned to the Laboratory. Biological assays, some chemical analyses, and field activities preparation are performed by ESB staff at the Laboratory. The following highly-automated equipment are operated, with exceptions, by the ESAT contractor:

- four gas chromatographs (GC)
- five GC/mass spectrometers (GC/MS)
- one high performance liquid chromatograph (HPLC)
- two inductively-coupled plasma atomic emission systems (ICP-AES)
- two atomic absorption spectrometers (AA)
- one cyanide autoanalyzer
- one ion chromatograph (IC)
- one total organic carbon (TOC) analyzer
- one total organic halide (TOX) analyzer

Adjunct facilities based at the Laboratory include a mobile laboratory and two boats operated by ESB staff and a Field Analytical Support Project (FASP) laboratory containing three GCs and an AA dedicated to Superfund investigations, which is maintained and operated by ESAT under ESB direction.

Procurement and delivery of laboratory services. Before samples are analyzed in the Laboratory, a FSP is prepared by the requester, and reviewed, and approved by QAMS/ESB. Exceptions to this must be approved by the RQAM. This policy is designed to produce analytical requests that are technically sound and meet the data quality needs of the program. The written plan is also a basis for the communication of the requester's analytical needs to the Laboratory. These needs as well as sample shipping information are provided to the Laboratory by the Regional Sample Control Coordinator (RSCC).

Within 30 days of sample receipt a data package containing the analytical results, raw data and laboratory QC results is completed. The package is assembled in a standard format which permits efficient data review. It is reviewed by Laboratory staff for correctness, completeness, and compliance with established criteria, and transmitted to the LS Chief. The data are validated under the supervision of the QAMS Chief before submittal to the client.

10.2 QA PROGRAM

Region 9 is committed to monitoring and optimizing the Laboratory's performance through a variety of QA activities. These activities are implemented under the leadership of a Laboratory QA manager, and will be documented in a Laboratory QA Plan (in progress).

The Laboratory routinely analyzes QA/QC samples along with field samples as a basis for determining laboratory performance. The specific QA/QC requirements vary with the program, and are specified in the FSP. The Laboratory also analyzes PE samples from the Superfund, Drinking Water, and NPDES programs. Occasional double-blind or single-blind samples are also provided as part of the laboratory oversight program (the Laboratory is used as a reference laboratory).

The quality of the sampling data generated by the Laboratory is monitored through the routine data validation by QAMS/ESB of all data packages submitted. A laboratory audit is scheduled bi-annually by the RQAM and performed by QAMS/ESB. When corrective action is indicated, the LS chief, the Laboratory Team Leader, and the Laboratory QA Manager are responsible for implementing the necessary changes.

SOPs for routine activities are prepared, reviewed, and updated as needed. The responsibility for review and approval of the SOPs rests with the Laboratory Team Leader, the Laboratory QA Manager, and the LS Chief.

SECTION 11
ACRONYM LIST

BOP. Branch Operating Plan.

CFR. Code of Federal Regulation.
CLP. Contract Laboratory Program.
CLP-TPO. Contract Laboratory Program Technical Project Officer.
CO. Contracting Officer.

DQOs. Data Quality Objectives.

EDCA. Environmental Data Collection Activity.
ESAT. Environmental Services Assistance Team.
ESB. Environmental Services Branch.

FAR. Federal Acquisition Regulations.
FASP. Field Analytical Support Program.
FRC. Federal Records Center.
FSP. Field Sample Plan.
FST/ESB. Field Services Team/Environmental Services Branch.

HQ. Headquarters.
HRMB. Human Resources Management Branch.

IG/ORC. Inspector General/Office of Regional Counsel.
IRM. Information Resources Management.

LS/ESB. Laboratory Section/Environmental Services Branch.

MSR. Management System Review.

NERL-CIN. National Exposure Research Laboratory, Cincinnati.
NPDES. National Pollution Discharge Elimination System.

OARM. Office of Administration & Resources Management.
OPM. Office of Policy and Management.
ORD. Office of Research & Development.
OSWER. Office of Solid Waste & Emergency Response.

PE. Performance Evaluation.

QA. Quality Assurance.
QAMS/ESB. Quality Assurance Management Section/Environmental Services Branch.

QAMS/ORD. Quality Assurance Management Section/Office of Research & Development.
QAPjP. Quality Assurance Project Plan.
QAPP. Quality Assurance Program Plan.
QATS Laboratory. Quality Assurance Technical Support Laboratory
QC. Quality Control.

RA. Regional Administrator.
RMO. Records Management Officer.
RQAM. Regional Quality Assurance Manager.
RSCC. Regional Sample Control Coordinator.

SOP. Standard Operating Procedure.
STARS. Strategic Targeted Activities for Results System.
STORET. Storage and Retrieval (database).

TPO. Technical Project Officer.
TQI. Total Quality Improvement.
TQM. Total Quality Management.
TSA. Technical Systems Audit.

UIC. Underground Injection Control

WQM. Water Quality Monitoring.